EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #121
(Defendants' Motion for an Order Requiring Preservation of Explanted Mesh)

This multidistrict litigation ("MDL") involves claims that Ethicon, Inc. improperly designed, manufactured, marketed, and sold defective surgical mesh products to thousands of women to treat pelvic organ prolapse and stress urinary incontinence. As a result of alleged complications from the mesh, a portion of the plaintiffs herein have sought or will seek surgical removal of the mesh material. Currently pending before the court is Defendants' motion for an Order requiring Plaintiffs to (1) notify their health care providers of the duty to preserve explanted mesh material and (2) provide Defendants with one half of the explanted material in a condition that enables Defendants to do their own testing on the evidence. (ECF No. 1159). On Friday, June 13, 2014, the undersigned heard oral argument on the motion at the request of Plaintiffs. Having fully considered the arguments of counsel, and for the reasons that follow, the court **GRANTS** the motion for an Order Requiring Preservation as set forth herein.

I. The Motion and the Parties' Positions

According to Defendants, they are compelled to file this motion requesting court intervention after spending considerable time unsuccessfully negotiating a preservation protocol with Plaintiffs. Meanwhile, mesh removal surgeries are purportedly occurring without any effort on the part of individual plaintiffs to preserve the mesh specimens.

Plaintiffs filed a response in opposition to the motion. (ECF No. 1178). Although they agree generally that a preservation order is appropriate, they disagree with Defendants' request that the court order Plaintiffs to preserve all of the explanted mesh and provide no guidance on when and how the preservation should be accomplished. Plaintiffs contend that the duty to preserve explanted mesh should not exist in every case, but should be triggered only when a case is selected for trial preparation. In addition, Plaintiffs argue that a specific protocol should be implemented that sets forth with particularity the manner and method by which the explanted materials should be preserved and divided between the parties. Plaintiffs resist being left with the unilateral duty of preserving and maintaining the explanted mesh for fear that Defendants will attack the Plaintiffs' selected method in hindsight.

Defendants filed a reply memorandum, stating that explanted mesh must be preserved in all cases given that it is critical evidence. (ECF No. 1186). Defendants further assert that they have no right or duty to define the specifics of how Plaintiffs' mesh should be preserved. Instead, that obligation rests solely with Plaintiffs. Defendants urge the court that it should avoid putting its imprimatur on a specific preservation method; particularly, as the experts disagree as to which solution—saline, formalin, or formaldehyde—is the best preservative for explanted mesh. In Defendants view, they "must not be placed in the position of acceding to an order which approves

the proposed method of preservation which also prejudices their ability to conduct the testing necessary to contest Plaintiffs' claims." (*Id.* at 4).

Finally, Plaintiffs filed a sur-reply in which they suggest that explanted mesh is similar to medical records and, thus, is not within their control or custody for discovery purposes. (ECF No. 1215). Consequently, Plaintiffs have no greater ability, or responsibility, to obtain and preserve explanted mesh. They argue that requiring explanted mesh to be preserved in every pending case would create an extraordinary and unnecessary burden on health care providers. Lastly, Plaintiffs assert that fairness requires the implementation of a protocol governing the receipt, division, and preservation of mesh specimens.

II. Discussion

At the outset of the hearing, the parties agreed that mesh surgically removed from a plaintiff in this MDL constitutes material evidence. The law in this circuit is well-settled that a party has a duty to preserve material evidence when the party "reasonably should know that the evidence may be relevant to anticipated litigation." *Silvestri v. General Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001) (citing *Kronisch v. United States,* 150 F.3d 112, 126 (2nd Cir. 1998)). This duty requires the party to "identify, locate, and maintain information that is relevant to specific, predictable, and identifiable litigation" and to "notify the opposing party of evidence in the hands of third parties." *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 522-23 (D.Md. 2010) (citations omitted). In the Fourth Circuit, a party who does not possess or own the evidence may still have control over it "when that party has the right, authority, or practical ability to obtain [the evidence] from a non-party to the action." *Id.* at 523 (quoting *Goodman v. Praxair Services, Inc.*, 632 F.Supp.2d 494, 515 (D.Md. 2009)).

A. Duty Rests with All Plaintiffs

Plaintiffs make the unsupported argument that they have no greater duty than Defendants to ensure that medical facilities preserve their explanted mesh specimens. For several obvious reasons, they are wrong. First, Plaintiffs are in the best position to know that the mesh evidence exists considering that they are the individuals from whom the mesh is removed. Defendants have no practical way of knowing when and where an individual plaintiff will have surgery that involves the removal of Ethicon's mesh. Until the mesh is removed, it is not a piece of evidence subject to preservation, division, and testing. Second, Plaintiffs have the closest relationship with their health care providers. They have both the physical proximity and the legal authority to timely request that their mesh specimens be preserved.

Third, the removed mesh belongs to Plaintiffs, or certainly is in their control. Plaintiffs cite to a number of cases involving the concept of "possession, custody, or control" of medical records when viewed in the context of Federal Rule of Civil Procedure 34 to argue by analogy that they have no control over the mesh explants. These cases are inapposite. As a general rule, medical records belong to the health care provider that creates them, as they embody the work, thought processes, and analysis of the provider. The patient has a right to access the records, but has no right to possess, control, or take custody of them. On the other hand, foreign objects removed from a patient's body during surgery, such as explanted medical devices, are usually not considered the property or work product of the laboratory receiving them. They are not customarily maintained as part of a medical record, and are routinely discarded if not requested by the patients, law enforcement, or the removing surgeon. Many health care facilities have policies and procedures that govern the release of foreign objects removed

during surgery to patient, physicians, and others for legal purposes. Consequently, even if the mesh explants arguably do not belong to them, Plaintiffs certainly have considerable control over the explants given that Plaintiffs have the practical ability to obtain the explants from the health care facilities before they are discarded. At the very least, Plaintiffs have the opportunity to notify Defendants that a specific piece of mesh is being held by a health care facility after an explant surgery.

The undersigned also rejects Plaintiffs' contention that, for convenience sake, the duty to preserve explanted mesh should be triggered only when a case is selected for trial preparation. This court has no authority or inclination to pick and choose which Plaintiffs are required to fulfill their evidence preservation obligation and which may be excused. Furthermore, the MDL is not in a posture that allows the court to predict with any certainty the number of remaining cases that will be tried or remanded, dismissed or settled, let alone which cases will proceed in each direction.

Accordingly, the court **ORDERS** that **all** Plaintiffs in this MDL are required to take reasonable steps to preserve their explanted mesh material. Plaintiffs shall notify their counsel of any planned or completed surgery involving the removal of mesh material; shall notify their health care provider of the duty to preserve explanted mesh material; and shall take any necessary steps to facilitate preservation of the explanted mesh at the site of removal until arrangements can be made to deliver it to a third-party repository.

B. Manner of Preservation

The second issue raised by the parties is the method by which the mesh explants should be preserved and handled by the health care facility receiving the explant as a surgical specimen at the time of its removal. Plaintiffs seek the entry of a detailed order

that requires the health care facility to take various steps dictated by the parties herein, culminating in release of the explant to a third-party repository. In contrast, Defendants refuse to make any suggestions at all. They take no position on how the evidence should be maintained and preserved, advance no particular protocol, and seek no role in managing the mesh explants. Rather, Defendants want permission to sit on the sideline, while the court requires Plaintiffs to "take whatever steps may be appropriate to preserve this evidence for whatever testing may be required by both Plaintiffs and Defendants." (ECF No. 1159 at 4). Neither of these proposals is acceptable.

For the reasons discussed at the hearing, the court does not feel that the parties can or should rely on health care facilities to deviate from their protocols and policies to act as managers and custodians of evidence for this MDL. Therefore, the court **ORDERS** each plaintiff from whom mesh is removed to notify the health care facility that takes possession of the mesh at the time of its removal that the plaintiff wishes to have the mesh returned or released to her. The plaintiff shall follow the policy or protocol of the health care facility in obtaining the mesh explant. The manner of preserving the mesh explant until its release to the plaintiff shall be determined by the health care facility. When the health care facility is prepared to release the explant, the explant shall be transferred to an independent third party repository to be determined by the parties. The parties are **ORDERED** to meet and confer regarding the protocols governing the transfer, preservation, and division of mesh explants after they are released by the health care facility.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action

number 2:14-cv-18461. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at **http://www.wvsd.uscourts.gov**.

ENTERED: June 17, 2014.

Cheryl A. Eifert
United States Magistrate Judge